NOV 10 2008

510(k) Summary

Company Name: SeaSpine, Inc.
2302 La Mirada Drive
Vista, CA 92081

Contact Person: Jeff Brittan
Senior Project Engineer
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Date Prepared: August 11, 2008

Trade Name: SeaSpine Spacer System – Hollywood™, Pacifica™, Redondo™, Ventura™

Common Name: Vertebral Body Replacement Device
Interbody Fusion Device

Classification Name: Spinal Intervertebral Body Fixation Orthosis
Intervertebral Body Fusion Device

Classification Number (s)/Product Codes(s): 21 CFR 888.3060, Product Code MQP, Class II
Orthopedic Review Committee
21 CFR 888.3080, Product Code MAX, Class II
Orthopedic Review Committee

Device Description: The SeaSpine Spacer System is an implantable device made from polyetheretherketone (PEEK) with markers for radiographic visualization. The device has a central canal for receiving bone graft and is offered in a variety of sizes and geometries to accommodate variations in pathology and patient anatomy.

Intended Use: When used as an intervertebral body fusion device, the SeaSpine Spacer System is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autogenous bone graft and supplemental fixation.

When used as a vertebral body replacement device (VBR), the SeaSpine Spacer System is intended for use in the thoracolumbar spine (T1 to L5) to replace a collapsed, diseased, damaged or unstable complete or partial

	vertebral body due to tumor or trauma/fracture, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The SeaSpine Spacer System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of fusion for a prolonged period. Additionally, the device is intended for use with bone graft.
Substantial Equivalence:	The SeaSpine Spacer System was shown to be substantially equivalent to the predicate devices through comparison in areas including use, design, materials, and function.
Performance Data:	Mechanical testing results indicated that the SeaSpine Spacer System possessed appropriate properties for its intended use and is substantially equivalent to the predicate devices. Clinical data was not required for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SeaSpine, Inc.
% Mr. Jeffrey Brittan
Senior Project Engineer
2302 La Mirada Drive
Vista, California 92081-7862

NOV 10 2008

Re: K082310
Trade/Device Name: SeaSpine Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX, MQP
Dated: August 11, 2008
Received: August 13, 2008

Dear Mr. Brittan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082310

Device Name: SeaSpine Spacer System

Indications for Use:

When used as an intervertebral body fusion device, the SeaSpine Spacer System is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autogenous bone graft and supplemental fixation.

When used as a vertebral body replacement device (VBR), the SeaSpine Spacer System is intended for use in the thoracolumbar spine (T1 to L5) to replace a collapsed, diseased, damaged or unstable complete or partial vertebral body due to tumor or trauma/fracture, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The SeaSpine Spacer System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of fusion for a prolonged period. Additionally, the device is intended for use with bone graft.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082310